AF/3738
IPW

TRANSMITTAL OF APPEAL BRIEF

Docket No.
NY-HUBR 1099-US

In re Application of: Johannes Reinmuller

Application No.	Filing Date	Examiner	Group Art Unit
08/732,408	December 9, 1996	B. E. Pellegrino	3738

Invention: MEDICAL IMPLANTS MADE OF MOULDINGS

TO THE COMMISSIONER OF PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: June 10, 2005 .

The fee for filing this Appeal Brief is $ 250.00 .

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☐ A petition for extension of time is also enclosed.

The fee for the extension of time is _____ .

☒ A check in the amount of $ 250.00 is enclosed.

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☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-0624 .
This sheet is submitted in duplicate.

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Dated: 8/3/05

Appeal Brief Transmittal

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 8/3/05 Signature: Eileen Sheffield (Eileen Sheffield)

HUBR-1099 (09883564)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Reinmuller
Serial No.	:	08/732,408
Filed	:	December 9, 1996
For	:	MEDICAL IMPLANTS MADE OF MOULDINGS
Art Unit	:	3738
Examiner	:	B. E. Pellegrino

August 3, 2005

This correspondence is being sent by first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 on the date shown below:

Eileen Sheffield Date: 8/3/05

MS: Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on June 10, 2005, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are addressed in the accompanying Transmittal of Appeal Brief.

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(I) REAL PARTY IN INTEREST

The real party in interest is the inventor Johannes Reinmuller.

(II) RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

(III) STATUS OF CLAIMS

Claims 1-128 and 171-174 are canceled.

Claims 129-170 and 175-181 are pending and are finally rejected.

(IV) STATUS OF AMENDMENTS

All amendments except the Rule 116 Amendment of July 26, 2005, have been entered. It is believed that amendment will be entered and the claims appended hereto reflect entry of that amendment

(V) SUMMARY OF THE CLAIMED SUBJECT MATTER

The claimed invention relates to a medical implant which has compression elasticity and tissue-like properties along with long term chemical stability without diffusion of lower molecular toxic components into the surrounding tissue. (page 3, lines 14-20). The medical implants of the present invention are based on solid, spaghetti shaped strands contained or surrounded by an outer covering. (See page 5, lines 14-16 and page 7, lines 24-26, Example 1, p. 10 and Figs. 1-3).

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Did the Examiner err by finally rejecting claims 129-132, 135-141, 147, 149, 152-155, 160 and 167-181, as allegedly anticipated under 35 U.S.C. §102(e) by U.S. Patent No. 5,534,023 to Henley ("Henley")?

2. Did the Examiner err by finally rejecting claims 133, 134 and 158 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of U.S. Patent No. 5,496,367 to Fisher ("Fisher")?

3. Did the Examiner err by finally rejecting claims 142, 144-146, 148 and 150 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of U.S. Patent No. 5,607,590 to Shimizu ("Shimizu")?

4. Did the Examiner err by rejecting claims 156 and 157 under 35 U.S.C. §103 as allegedly obvious over Henley in view of U.S. Patent No. 5,282,857 to Perry et al.("Perry")?

5. Did the Examiner err by rejecting claims 143, 161 and 162 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of U.S. Patent No. 4,657,553 to Taylor ("Taylor")?

6. Did the Examiner err by rejecting claim 159 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of Shimizu further in view of Fisher?

7. Did the Examiner err by rejecting claim 163 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of Fisher and U.S. Patent No. 4,348,329 to Chapman ("Chapman")?

8. Did the Examiner err by rejecting claims 164-166 under 35 U.S.C. §103(a) as allegedly obvious over Henley in view of European Patent Application No. 322194 A1 to Ledergerber?

(VII) ARGUMENT

a) 102(e) Rejection of Claims 129-132, 135-141, 147, 149, 152-155, 160, 167-181 over Henley

Henley discloses an air-filled silicon material which has air filled beads or chambers connected together by extrudate chains that the Examiner interprets as "spaghetti-like strands". Appellant asserts that Henley does not disclose "spaghetti-like strands", which are solid and not interrupted by such air-filled beads or chambers. Simply, what Henley discloses are not spaghetti-like strands as claimed. Therefore, each and every limitation of the claims is not disclosed by Henley, and, therefore, the claims are not anticipated.

Furthermore, it is respectfully submitted that Henley's gas filled beads could be compressed or deform, unlike Appellant's solid, spaghetti-like strands, leading to breaking or to a non-uniform implant. Thus, it may not be as durable as the spaghetti-like strands of the present invention.

With respect to claims 129, 131, 136 and 139, the Examiner also alleges that Henley describes a "continuous solid spaghetti-like strand." However, Henley discloses gas filled beads that interrupt the continuous, solid spaghetti-like strands surrounded by the outer covering.

With respect to claim 130 and 138, Henley's "beaded" strand contains air chambers, and, therefore, does not "consist of" silicone rubber as claimed.

With regard to claim 131 and 141, Henley does not disclose a solid, continuous spaghetti-like strand made of plastic.

With respect to claim 135, the Examiner alleges that anything can be considered wettable, but provides no objective evidence.

With respect to claim 140, it is not believed that Henley discloses that the covering is made of plastic or silicone rubber.

With respect to claim 147, 149, 152, 153, 155, 160, Henley does not disclose an outer covering containing therein at least one continuous, solid spaghetti-like strand (as discussed above, e.g., with respect to claim 129, et al.) made of a physiologically compatible material having a surface wettable by a fluid lubricant, although Henley does disclose that lubricants can be added.

With respect to claim 155, Henley does not appear to disclose that the fluid lubricant is selected from a polysaccharide and a glucosaminoglycan.

As to claims 167-170, in addition to the above, Henley does not disclose that the implant should comprise a plurality of the spaghetti-like strands.

The rejection of claims 171-174 has been rendered moot by cancellation of these claims.

b) §103(a) rejection of claims 133, 145 and 158 as allegedly obvious over Henley and Fischer

As noted above, Henley fails to disclose, *inter alia*, solid spaghetti-like strands for use in an implant. Fisher is cited for disclosing use of plastic for structural material in an implant. However, Fisher does not disclose that plastic may be used in a spaghetti-like strand in an

implant, and the references provide no motivation to do so. Therefore, there is no reason to combine these references as alleged by the Examiner. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143.

Claim 134 relates to a plastic material so the rejection is not believed to be applicable. To the extent it may be, Henley does not disclose that the implant surface should be wettable.

c) **103(a) rejection of claims 142, 144-146, 148 and 150 over Henley and Shimizu**

Henley, *inter alia*, fails to disclose the spaghetti-like strands and that the surface is hydrophilized. Shimizu is cited for disclosing that silicone surfaces can be hydrophilized such that it increases the affinity for living tissue or potential tissue ingrowth. There is, however, no hint or suggestion in these references to hydrophilize the outer covering of an implant containing spaghetti-like strands as in claim 142, 144, 145, 148 and 150.

With respect to claim 146, the outer covering of the spaghetti-like strand is hydrophilized, and since it is contained inside a covering and does not directly contact body tissue, so there is no motivation to hyrophilize the surface provided by Shimizu.

d) **103(a) rejections of claims 156 and 157 as allegedly obvious over Henley and Perry**

Henley fails to disclose the spaghetti-like strands as discussed above, and also fails to disclose using fat or oil as a lubricant. Perry is cited for disclosing that fats or oils in the form of glycerides are used in implants. There is no motivation, however, to contain a fat or oil lubricant in an implant having spaghetti-like strands in an outer covering as claimed.

e) **103(a) rejection of claims 143, 161 and 162 over Henley and Taylor**

Henley fails to disclose spaghetti-like strands used in an implant, and also fails to disclose the use of polysaccharides or polydimethylsiloxane as the implant material. Taylor is cited for disclosing that polysaccharides are used in soft implants and can be hydrophilic, and that polydimethylsiloxane is used in constructing medical implant material. There is no motivation, however, to use such materials in an implant made with spaghetti-like strands as presently claimed.

f) **103(a) rejection of claim 159 over Henley, Shimizu and Fisher**

The deficiencies of the combination of Henley and Shimizu are described above in Fisher is cited for disclosing the use of plastic as an implant material, a feature not disclosed by the combination of Henley and Shimizu. There is no motivation, however, to provide a spaghetti-like strand, furthermore made of plastic. Furthermore, it is not readily apparent that one could use plastics with Henley's chains of gas-filled beads, as rigidity may become of factor in use as an implant. Motivation to make the Examiner's proposed modification, is, therefore, lacking.

g) **103(a) rejection of claim 163 over Henley, Fisher and Chapman**

Deficiencies of Henley and Fisher are discussed above.

It is not believed that one would be motivated to produce Henley's strands of gas filled beads with a plastic material. Chapman is cited for disclosing the use of cuprophane but it is not believed there is motivation in the cited references to prepare Henley's beaded chains of any plastic, and let alone cuprophane.

h) 103(a) rejection of claims 164-166 over Henley and Ledergerber

Henley fails to disclose spaghetti-like strands and a foam structure in the implant or x-ray medium incorporated in the implant. Ledergerber is cited for disclosing that foam can be used in the implant and that an x-ray contrast medium can be incorporated into the material. There is no motivation in the cited references, however, to use foam or to incorporate an x-ray contrast medium into an implant containing spaghetti-like strands as claimed.

If any additional fees are due, authorization is given to charge deposit account no: 50-0624.

In view of the foregoing, Appellants respectfully request reversal of all rejections.

Respectfully submitted,

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CLAIMS APPENDIX

1-128 (canceled)

129. A medical implant comprising at least one continuous, solid spaghetti-like strand comprising a physiologically compatible material surrounded by an outer covering.

130. The medical implant of claim 129, wherein said spaghetti-like strand consists of silicone rubber.

131. The medical implant of claim 129, wherein said spaghetti-like strand comprises silicon rubber.

132. The medical implant of claim 129, wherein said spaghetti-like strand comprises plastic.

133. The medical implant of claim 129, wherein said physiologically compatible material is plastic or silicone rubber.

134. The medical implant of claim 130, having a wettable surface.

135. The medical implant of claim 129, having a wettable surface.

136. The medical implant of claim 129, wherein said outer covering is made of a physiologically compatible material.

137. The medical implant of claim 136, wherein said outer covering is made of plastic or silicone rubber.

138. The medical implant of claim 130, wherein said outer covering is made of a physiologically compatible material.

139. The medical implant of claim 131 wherein said outer covering is made of a physiologically compatible material.

140. The medical implant of claim 139, wherein said outer covering is made of plastic or silicone rubber.

141. The medical implant of claim 132, wherein said outer covering is made of a physiologically compatible material.

142. The medical implant of claim 129, wherein a surface of said outer covering is hydrophilized.

143. The medical implant of claim 129, wherein a surface of said structural element has a hydrophilized surface.

144. The medical implant of claim 142, wherein said structural element is a spaghetti-like strand.

145. The medical implant of claim 144, wherein said spaghetti-like strand comprises silicone rubber.

146. The medical implant of claim 144, wherein the outer surface of said spaghetti-like strand is hydrophilized.

147. A medical implant comprising an outer covering containing therein at least one continuous, solid spaghetti-like strand made of a physiologically compatible material having a surface that is wettable by a fluid lubricant.

148. The medical implant of claim 147, wherein said implant has a hydrophilized surface.

149. The medical implant of claim 147, wherein said physiologically compatible material comprises silicon rubber.

150. The implant of claim 149, wherein the surface is hydrophilized surface and the lubricant is aqueous.

151. The implant of claim 148, wherein the fluid lubricant is aqueous.

152. The implant of claim 147, wherein the fluid lubricant is swellable.

153. The implant of claim 149, wherein the fluid lubricant is swellable.

154. The implant of claim 147, wherein the fluid lubricant is selected from the group consisting of a polysaccharide and a glucosaminoglycan.

155. The implant of claim 147, wherein a surface of the implant is hydrophobic.

156. The implant of claim 155, wherein said implant contains fat or oil wetting the hydrophobic surface as the fluid lubricant.

157. The implant of claim 155, wherein said implant contains fat as the hydrophobic surface as the fluid lubricant.

158. The implant of claim 147, wherein said physiologically compatible material is a plastic.

159. The implant of claim 148, wherein said physiologically compatible material is a plastic.

160. The implant of claim 155, wherein material said physiologically compatible material is a silicone rubber.

161. The implant of claim 147, wherein said physiologically compatible material is polydimethylsiloxane.

162. The implant of claim 147, wherein said physiologically compatible material is a polysaccharide.

163. The implant of claim 158, wherein the plastic is cuprophane.

164. The implant of claim 147, wherein the physiologically compatible material has a foam structure.

165. The implant of claim 147, wherein an X-ray contrast medium or a dye is incorporated into the physiologically compatible material.

166. The implant of claim 149, wherein an X-ray contrast medium or a dye is incorporated into the physiologically compatible material.

167. The implant of claim 130, comprising a plurality of spaghetti-like strands.

168. The implant of claim 132 comprising a plurality of spaghetti-like strands.

169. The implant of claim 147 comprising a plurality of spaghetti-like strands.

170. The implant of claim 149 comprising a plurality of spaghetti-like strands.

171-174 (canceled).

175. A method of implanting a medical implant into a subject comprising implanting an implant consisting of a continuous, solid spaghetti-like strand of silicon rubber in the desired site of a subject.

176. A method of implanting a medical implant comprising implanting the implant of claim 129 at a desired site of a subject.

177. A method of implanting a medical implant comprising implanting the implant of claim 130 at a desired site of a subject.

178. A method of implanting a medical implant comprising implanting the implant of claim 131 at a desired site of a subject.

179. A method of implanting a medical implant comprising implanting the implant of claim 147 at a desired site of a subject.

180. A method of implanting a medical implant comprising implanting the implant of claim 149 at a desired site of a subject.

181. The medical implant of claim 132, wherein said structural element has a wettable surface.